DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

49 CFR Part 571

[Docket No. NHTSA-2016-0021]

Federal Motor Vehicle Safety Standards; Occupant Crash Protection

AGENCY: National Highway Traffic Safety Administration (NHTSA), DOT.

ACTION: Denial of petition for rulemaking.

SUMMARY: This document denies a rulemaking petition submitted by Mr. James E. Hofferberth on April 1, 2013. His petition includes two requests: (1) To regulate the performance of supplementary automotive restraint systems that are marketed specifically for pregnant women; and (2) to require prominent warning labels in all vehicles with the intent of informing pregnant women that "seat belts could injure or kill their unborn child," specifically by crushing the unborn baby in a frontal crash. NHTSA is denying the petition to regulate the performance of these systems because the agency does not have sufficient information at this time to state whether there is an additional net safety benefit/disbenefit to be derived from their use or whether one type of device is superior to another. NHTSA is denying the petition for labeling because this would provide advice that, if followed, would threaten the safety of both the mother and the unborn child in a crash.

FOR FURTHER INFORMATION CONTACT:

For Non-Legal Issues: Mr. Louis Molino, Office of Crashworthiness Standards, National Highway Traffic Safety Administration, 1200 New Jersey Avenue, S.E., Washington, D.C. 20590, Telephone: (202) 366-1740, Facsimile: (202) 493-2990.

For Legal Issues: Mr. John D. Piazza, Office of Chief Counsel, National Highway Traffic Safety Administration, 1200 New Jersey Avenue, S.E., Washington, D.C. 20590, Telephone: (202) 366-2992, Facsimile: (202) 366-3820.

SUPPLEMENTARY INFORMATION:

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I. Background

In a letter dated April 1, 2013, Mr. James E. Hofferberth petitioned NHTSA to regulate the performance of supplementary automotive restraint systems for pregnant women and to also require prominent warning labels in all vehicles with the intent of informing pregnant women that "seat belts could injure or kill their unborn child." This is the petitioner's second request for rulemaking regarding the safety of seat belts for pregnant women.

A. Past Petition for Rulemaking

In 2005, NHTSA received a petition for rulemaking from this same petitioner, Mr. James E. Hofferberth, requesting that the agency initiate rulemaking to require an advisory placard warning occupants that seat belts should not be worn by pregnant women. On March 23, 2006,

NHTSA published a Federal Register notice (71 FR 14675) denying that petition because the requested warning label would provide advice that, if followed, would threaten the safety of both the mother and the unborn child in a crash.

B. Agency Position: Pregnant Women Should Wear Their Seat Belts

NHTSA recommends that pregnant women wear their seat belts, as does the American College of Obstetricians and Gynecologists (ACOG).[1] NHTSA publishes a flyer[2] developed in conjunction with ACOG and the National Healthy Babies Coalition that addresses this topic. The flyer describes the proper way for a pregnant woman to position her seat and to wear both the shoulder and lap belt portion of her seat belt, and it also explains that pregnant women should wear their seat belts even in vehicles equipped with air bags.

The safety benefits to pregnant women from wearing seat belts are supported by a research study,[3] which concluded that "[p]roper restraint use, with and without air bag deployment, generally leads to acceptable fetal outcomes in lower severity crashes, while it does not affect fetal outcome in high-severity crashes." The study concluded that "compared to properly restrained pregnant occupants, improperly restrained occupants have a higher risk of adverse fetal outcome in lower severity crashes." It is also recommended that all pregnant women seek medical attention after a car crash regardless of the severity of maternal injury.

[1] American College of Obstetricians and Gynecologists. "Car Safety for You and Your Baby, Frequently Asked Questions: FAQ018, Pregnancy," August 2011, *http://www.acog.org/~/media/For%20Patients/faq018.pdf?dmc=1&ts=20130603T1624145840*.
[2] NHTSA, The Pregnant Woman's Guide to Buckling Up, Your Top 5 Seat Belt Questions Answered, March 2010, *http://www.trafficsafetymarketing.gov/newtsm/tk-bua/PregnantWomenSeatBeltFlyer.pdf*.
[3] Klinich, K. D., Schneidier, L. W., Moore, J. L., Pearlman, M. D., entitled "Investigations of Crashes Involving Pregnant Occupants," dated 1999. This work was supported by General Motors Corporation, pursuant to an agreement with the U.S. Department of Transportation.

NHTSA and other experts agree that the best way to protect an unborn child is to protect the mother.[4]

C. Pregnant Women in Motor Vehicle Crashes

The agency conducted an extensive review in its analysis of the petition. This included a review of technical literature, including a study by the University of Michigan Transportation Research Institute (UMTRI), as well as the papers cited by the petitioner. The agency also conducted a full review of the NHTSA field data repositories for evidence of supplementary automotive restraints causing harm to pregnant women in motor vehicle crashes (MVCs). The agency's findings are provided in the following sections of this notice, and they reaffirm the position stated in the 2006 denial notice.

1. Past Studies

NHTSA has sponsored research studying and demonstrating the effectiveness of properly adjusted restraint systems for pregnant women from as early as 1971,[5] when seat belts composed of both a lap and shoulder portion were not as prevalent as they are today. Other research, independent of NHTSA, has also been conducted, and both biomedical research and restraint technologies have advanced over time. For example, a 1998 paper written by researchers at UMTRI explains that the unborn baby is protected by amniotic fluid, which isolates the unborn baby by acting as a shock absorber.[6] This amniotic fluid is what naturally resists the forces from

[4] Duma, S., Moorcroft, D., Stitzel, J., Duma, G., entitled "A Computational Model of the Pregnant Occupant: Effects of Restraint Usage and Occupant Position in Fetal Injury Risk," published June 2005 in the Proceedings of the 19th International Technical Conference on the Enhanced Safety of Vehicles.
[5] King, A. I., Crosby, W. M., Stout, L. C., Eppinger, R. H., entitled "Effects of Lap Belt and Three-Point Restraints on Pregnant Baboons Subjected to Deceleration," published in 1971 in the 15th Stapp Crash Conference Proceedings and the Society of Automotive Engineers as paper #710850.
[6] Klinich, K. D., Schneider, L. W., Moore, J. L., Pearlman, M. D., entitled "Injuries to Pregnant Occupants in Automotive Crashes," published October 1998 in the 42nd Annual Proceedings of the Association for the Advancement of Automotive Medicine.

the lap portion of a seat belt, and it prevents the belt from penetrating through the unborn baby's body. Mr. Hofferberth's petition claims that the belt penetrates through the unborn baby's body.

More recently, a 2008 paper written by these same researchers at UMTRI[7] summarized a study in which in-depth investigations of MVCs involving pregnant women were conducted, with a focus on determining how restraint conditions and specific crash characteristics had affected the outcome of the unborn baby. Studies conducted up to this point generally did not include complete and accurate information about crash severity and restraint use, or they emphasized crashes with adverse outcomes for the unborn babies in order to illustrate unusual and/or severe injuries. By including crashes with both positive and adverse outcomes for the unborn baby and also studying both belted and unbelted pregnant women, this study provided medical practitioners and safety engineers more of a comprehensive, quantitative analysis for giving advice to pregnant women and improving the design of vehicle restraints.

The 57 investigated cases all involved women of at least 20 weeks gestation who were involved in a motor vehicle crash that was not a rollover and who agreed to participate. Natural spontaneous pregnancy loss before 20 weeks of gestation being not uncommon, which made association of fetal loss so early in pregnancy with an MVC questionable, and the difficulty in determining injury causation to occupants during a rollover event[8] resulted in cases with these two factors being excluded. Case subject interviews and examinations of physical evidence were used to determine seat belt use, and estimated change in velocity (delta-V) from a crash reconstruction program was used to determine crash severity. The outcome of the unborn baby

[7] Klinich, K. D., Flannagan, C. A., Rupp, J. D., et al, entitled, "Fetal outcome in motor-vehicle crashes: effects of crash characteristics and maternal restraint," published April 2008 in the American Journal of Obstetrics & Gynecology.

[8] Excluding rollover events may have created a slight bias in the database. The paper states that "…rollovers account for only 2 percent of all crashes annually in the United States. The effect of this exclusion is therefore expected to have minimal impact on the study findings."

was studied for a period of one month after the crash took place, and these outcomes were classified as either good, minor complications, major complications, or fetal loss. Injuries to the mothers were classified using the Injury Severity Score (ISS), excluding injuries to the placenta or uterus, and these scores were used to classify the mothers' injuries as either nonexistent, minor, moderate, or major. Maternal death was also tracked, regardless of the mother's ISS. Restraints were classified as either proper (3-point belt or 3-point belt plus air bag) or improper (unrestrained, air bag only, and shoulder belt only with air bag, and shoulder belt only without air bag).[9]

The database created by this study became the largest collection of MVCs involving pregnant women including detailed quantitative information about both the crash event and the outcome for the unborn baby, with a focus on crashes with both positive and negative fetal outcomes. The seat belt usage rate in the database was reported as 72 percent,[10] and the study results showed a positive effect on fetal outcome from the mother's proper use of a seat belt during a crash. The statistical risk curves from this study's data analysis "indicate[d] that an 84 percent reduction in risk of adverse fetal outcome is obtained by properly wearing a seatbelt. On the basis of this relative risk and an overall belt use rate of 80 percent, unbelted pregnant women sustain an estimated 62 percent of all fetal losses in motor vehicle crashes . . . Crash severity is the factor most strongly associated with fetal outcome . . . Claims that restraints cause adverse fetal outcomes cannot be substantiated without reliable information on crash severity . . . [M]aternal injury is predictive of fetal outcome, and proper restraint use reduces maternal injury severity."

[9] None of the maternal occupants in the cases studied wore only a lap belt.
[10] This statistic was reported in the 2008 Klinich paper, referring to the 2005 NHTSA report, DOT HS 810 623, Traffic Safety Facts 2005. A more specific comparison would be the seat belt use rate for women of likely childbearing age.

2. Available Field Data

a) Data Sources

To analyze the claims in the petition, the agency studied crashes involving pregnant women in the applicable NHTSA data repositories: Artemis,[11] the Fatality Analysis Reporting System (FARS),[12] the National Automotive Sampling System (NASS) Crashworthiness Data System (CDS),[13] and the Special Crash Investigations (SCI) program.[14] Artemis does not currently contain any entries related to complaints or reported injuries resulting from the use of supplemental restraint devices. Although FARS does capture information about fetal demise, its fetal demise data-capturing capabilities are limited because it utilizes the American National Standards Institute (ANSI) definition[15] of a person as "any living human . . . [A] fetus is considered to be part of a pregnant woman rather than a separate individual."[16] Hence, FARS only captures information about fetal demise if someone else involved in the crash also expired. NASS CDS and SCI cases were also consulted for the following analysis. Though the sample of pregnant women in NASS CDS is relatively small, it is an appropriate and applicable source of data to explore the crash risks for this cohort because it is from a nationally representative

[11] Artemis is the agency's repository of motor vehicle and motor vehicle equipment defects. It contains consumer complaints and manufacturer early warning and reporting information, recalls, and safety defect investigations.
[12] FARS is a census of fatal motor vehicle crashes from 1975 to the present from the fifty States, the District of Columbia, and Puerto Rico. To qualify as a FARS case, the death of either a non-motorist or a motorist must occur within 30 days of the crash and the vehicle must be traveling on a trafficway customarily open to the public.
[13] NASS CDS is a database containing a probability sample of all police reported crashes in the U.S. Cases are chosen from all police reported crashes involving a harmful event (property damage and/or personal injury) resulting from a crash and involving at least one towed passenger car, light truck, or van in transport on a trafficway.
[14] SCI cases are selective, highly detailed and in-depth crash investigations using data from police and insurance reports as well as medical records, site and vehicle inspections, and interviews.
[15] DOT HS 811 694, 2011 Fatality Analysis Reporting System (FARS) and National Automotive Sampling System (NASS) General Estimates System (GES) Coding and Validation Manual, Page 5, Section 103.1, published 2012.
[16] Section 2.1.1 of standard ANSI D16.1-2007, the Manual on Classification of Motor Vehicle Traffic Accidents, Seventh Edition, prepared by the D16 Committee on Classification of Motor Vehicle Traffic Accidents under the direction of the Association of Transportation Safety Information Professionals of the National Safety Council Highway Traffic Safety Section and approved on August 2, 2007 by the American National Standards Institute, Inc. Board of Standards Review.

sample.[17] SCI cases are intended to provide an engineering perspective on anecdotal data, examining special crash circumstances or outcomes. As discussed below, an examination of NASS CDS and SCI data reaffirmed NHTSA's current position that pregnant women should wear a seat belt.

b) NASS CDS Data

NASS CDS started tracking fetal demise in 2006. The sampling is designed in such a way that it is possible to use the data to compute estimates representative of the entire country through application of a multiplier (case weight) to each NASS CDS case.[18] During this six-year time period there was a weighted estimate of 18,859,898 occupants of passenger vehicles involved in crashes qualifying as NASS CDS cases across the United States. Of these occupants, 0.6 percent [112,341/18,859,898] were pregnant women. The maternal fatality rate for this data set was 0.22 percent [245/112,341]. Where seat belt use was known, 85.0 percent of the pregnant women were reportedly wearing a seat belt and 15.0 percent were not.[19] Of the pregnant women reported to be wearing a seat belt, 99.7 percent [87,065/87,365] did not suffer a uterine or placental injury.

The weighted estimate of 112,341 pregnant women was derived from 439 unweighted cases. Twenty-four of these 439 cases were coded as involving the death of an unborn child. However, the agency believes that four of these cases were miscoded with respect to fetal

[17] In 2009, NASS CDS started collecting only partial occupant assessment records and no occupant injury records for vehicles more than 10 model years old. Information about occupant seat belt usage, a woman's pregnancy and the status of a fetus comes solely from a police report for these vehicles more than 10 model years old, and typically police reports subscribe to Section 2.1.1 of standard ANSI D16.1-2007 in regards to the fetus being considered an occupant.

[18] DOT HS 811 675, National Automotive Sampling System – Crashworthiness Data System 2011 Analytical User's Manual, Page 6, Section 3, "The Sampling System and Sample Design," published October 2012.

[19] The seat belt wearing status of 8.5 percent [9,533/112,341] of the pregnant females was reported as unknown. It should also be noted that those coded as wearing a seat belt were not necessarily wearing the seat belt correctly.

demise.[20] In addition, one of the twenty-four cases involved a crash for which a NASS investigator inspection of the vehicle was not permitted due to a pending legal case.[21] These five cases were excluded from the data set used for the analysis, and the 19 remaining cases correspond to a weighted estimate of 2,460 pregnant women who lost their unborn baby following a crash. The weighted data show that 2.2 percent of pregnant women lost an unborn child after being involved in a crash during this 6 year period, and 99.9 percent [87,251/87,365] of those known to be wearing a seat belt did not lose an unborn child due to a seat belt-caused uterine or placental injury.

Due to the small number of cases involving pregnant women who lost an unborn child after a crash and variation in the NASS CDS case weight factors applied to small numbers,[22] the following statistics associated with the data are provided for illustration only. The known belt use rate[23] for the fetal demise data set was 85.1 percent [2,094/2,460], which is nearly identical to the known belt use rate for the data set of 112,341 pregnant women previously described. The maternal fatality rate was 9.1 percent [223/2,460]. This is more than forty times the maternal fatality rate for the data set of all pregnant women (0.22 percent). The rate of placental injury in this data set was 42.4 percent [155/366] for the unbelted pregnant women, but only 5.4 percent [114/2,094] for the belted. Placental injuries sustained by the unbelted women were caused by contact with either the steering wheel or the ground after ejection from the vehicle. The maternal fatality rate for the unbelted occupants with fetal demise was 30.3 percent [111/366] but only 5.3 percent [112/2,094] for the belted occupants. For belted occupants, 94.6 percent [1,980/2,094]

[20] Cases 2007-43-199, 2008-43-24, 2009-43-188, and 2010-78-43 were flagged in the database as involving fetal demise, but they were excluded because examination of the case files provided convincing evidence that these were likely miscoded.
[21] Because both vehicle occupants perished in the crash, occupant interviews could not be conducted.
[22] The weight factor for the remaining 19 cases ranges from 8.35 to 594.
[23] Though all of these women did wear a seat belt, not all of them wore their seat belts correctly with the lap belt portion snug and low, across the hips.

of the pregnant women who lost an unborn child did not suffer a uterine or placental injury from the seat belt.[24] In other words, 94.6 percent of the time when a pregnant woman was wearing her seat belt and her unborn baby died in an MVC, the seat belt did not injure her uterus or placenta. Moreover, NASS CDS, a nationally representative sample, contains few cases of fetal demise, illustrating the rarity of this event.

c) NHTSA Case Studies

In order to be consistent with previous research in studying the deaths of unborn babies in frontal crashes, NHTSA aligned the NASS CDS data with that of the 2008 UMTRI study. This eliminated 18 of the 19 cases from the 2006-2011 NASS CDS dataset involving the death of an unborn child: eight cases[25] because they involved pregnant women in their first trimester, four cases[26] because they involved a rollover or other multi-event crash scenario, and six cases[27] because their principal direction of force (PDOF) did not indicate a frontal collision.[28] This left one case that was consistent with the UMTRI study's criteria. In addition, the agency included one case from the multi-event crash group in which the first event was a frontal impact and the second event was relatively minor. These cases are discussed below. This exercise demonstrated both the rarity of fetal demise in a vehicle crash as well as the complex nature of

[24] Injuries to the mother not caused by a seat belt tended to be from contact to other interior vehicle parts or from other sources such as the striking vehicle. In some cases injury causation could not be determined, and these cases were not included in calculating this value.
[25] NASS CDS cases 2006-47-56, 2006-75-212, 2007-41-1, 2007-48-128, 2007-72-119, 2008-11-21, 2008-75-5, and 2008-75-20.
[26] NASS CDS cases 2006-12-69, 2008-09-26, 2009-74-143, and 2011-13-152.
[27] NASS CDS cases 2006-73-35, 2006-73-106, 2007-76-25, 2008-75-84, 2010-48-127, and 2011-49-15.
[28] In addition to keeping an occupant inside of the vehicle during a rollover or side impact, a seat belt also holds an occupant into the seat during an event which would send an unrestrained occupant forward toward the steering wheel and windshield. It is during these forward motions that the seat belt becomes a potential source of injury to an unborn child, and these forward occupant motions are caused by frontal collisions where the vehicle's PDOF is pushing the car backwards. For this assessment a case was determined to be a frontal collision if the PDOF for the pregnant woman's vehicle was within ±45º of normal to the vehicle's frontal plane.

injury causation for a pregnant woman, further supporting the agency's position that pregnant women should wear a seat belt.

Case 2006-78-71

The one NASS CDS case that matched the 2008 UMTRI study criteria was case 2006-78-71. In this case, two vehicles were involved in a head-on collision. The 32 year old driver of the second vehicle, a 1993 Mazda 626 equipped with air bags, was 9 months pregnant and not wearing a seat belt. She was 150 cm tall and weighed 64 kg, with a Body Mass Index (BMI)[29] of 28.4. Crash reconstruction estimated the Delta-V to be 34 km/h longitudinally, and the NASS CDS investigator noted that there was no steering wheel rim/spoke deformation. The driver air bag did not deploy in this crash. The driver's most severe injury was an AIS 5[30] complex uterus laceration, judged to have certainly[31] been caused by direct contact with the steering wheel. She also had an AIS 2 minor mesentery laceration and an AIS 1 abrasion to her right hip, both also certain to have been caused by direct contact with the steering wheel. She was discharged from the hospital after 12 days, and medical records confirmed the death of the unborn baby.

Case 2008-09-26

This multi-event case from NASS CDS was also the focus of a NHTSA SCI investigation due to the concern that placental abruption was possibly caused by the seat belt. In this case, the vehicle containing the 40 year old pregnant woman, a 2006 Mercedes Benz E350, collided with a 2005 Ford Explorer Sport Trac attempting to make a left-hand turn. Crash reconstruction estimated the pregnant woman's vehicle to have a longitudinal Delta-V of 37 km/h. The

[29] Centers for Disease Control and Prevention (CDC). Healthy Weight – it's not a diet, it's a lifestyle!. September 13, 2011. *http://www.cdc.gov/healthyweight/assessing/bmi/adult_bmi/*.
[30] An AIS 5 is the highest survivable AIS score, with an AIS 6 indicating that a particular injury was unsurvivable.
[31] NASS CDS investigators must assign a confidence level to all injury sources. The choices for these levels in descending order of investigator confidence are "Certain," "Probable," "Possible," and "Unknown."

Mercedes struck the Ford forward of its center of gravity, causing the Ford to quickly rotate and strike the Mercedes in a side-slap impact. The pregnant woman was seated in the first row passenger seat and was wearing her seat belt, though it is unknown whether the seat belt was worn correctly. She was 165 cm tall and weighed 91 kg at the time of the crash, corresponding to a BMI of 33.4, placing her in the obese category.

The pregnant woman had 11 injuries with AIS scores ranging from 1 to 3. The most critical six were determined to have possibly resulted from contact with the driver and the center console during the side-slap, the most severe being an AIS 3 cerebrum subarachnoid hemorrhage. These injuries did not occur in the uterine area, and they were not directly related to the death of the unborn child. Injury number 7 of 11 was an AIS 3 lower placental abruption,[32] possibly caused by the belt webbing/buckle. The only other injury to the pregnant woman's uterine area was an abdominal skin contusion with the precise location unknown, possibly caused by the belt webbing/buckle.

While the crash was assigned to NHTSA's SCI team, the SCI investigators were not able to conduct interviews or inspect the vehicle until approximately 6 months after the crash. Though it was certain that the pregnant woman had been wearing her seat belt, investigators were not able to conclusively determine whether or not she had been wearing it correctly.

II. Current Petition

[32] The emergency personnel response time could not be determined for this case, though upon arrival at the scene, it was noted that the pregnant woman complained of head, chest, and abdominal pain with vaginal bleeding. She was transported by ground ambulance to a trauma center 10 miles away, where an ultrasound was immediately conducted, and a reduced fetal heartbeat was noted. The pregnant woman then had an emergency caesarian section, about 120 minutes post-crash, and a live 24.2 oz female baby was delivered in critical condition and transported to the Neonatal Intensive Care Unit (NICU). The baby died about 26 hours post-delivery due to premature birth as a consequence of the placental abruption.

Mr. Hofferberth petitions for two rulemakings. First, he requests that the agency initiate a rulemaking for Supplementary Automotive Restraint Systems for Pregnant Women. Second, the petitioner requests that the agency initiate rulemaking to require the warning of pregnant women that the seat belts could injure or kill their unborn children.[33] The petition includes a proposed performance specification and validation test procedure for supplementary restraint systems for pregnant women, including labelling, fit, position retention, strength, and stiffness requirements, as well as a design for a test platform. The petition also includes an unpublished report, "Prevention of Fetal Injury in Motor Vehicle Crashes," written by the petitioner.[34] The petitioner makes a number of factual assertions and arguments regarding his belief that the lap belt presents a significant hazard for the unborn child of a pregnant woman.

The petitioner, in both his letter and the attached report, states his beliefs that unborn babies are in danger of being crushed by the lap belt portion of a seat belt during a frontal collision and that seat belts are not appropriate for use by pregnant women. He cites research that he asserts shows that the lap belt portion of the restraint system has been implicated in causing specific trauma to the placenta and unborn child in relatively minor vehicular accidents. He also cites other research that he argues shows a high rate of fetal and placental injury and asserts that research shows that the fetus of a pregnant woman is approximately five times more likely to receive serious injury than a 0-1 year old child using a supplementary infant or child restraint riding in the same car.

[33] As explained above, and discussed in more detail below, this is contrary to NHTSA's considered view and the available evidence which establishes that pregnant women should wear their seat belts.

[34] In this report, the petitioner also states, as a "Recommendation," that NHTSA should update its recommended usage of the lap and shoulder belt by pregnant women to reflect the petitioner's views, as well as research the petitioner cites as supporting his views. Although this request is not a petition for rulemaking, the agency's decision on the petition for a warning label rulemaking is responsive to this suggestion. The petitioner also recommends that NHTSA initiate rulemaking requiring pregnant motor vehicle occupants to use a supplemental restraint system. NHTSA does not have statutory authority for such a rulemaking.

The petitioner also states that there are many supplementary restraint products on the market for pregnant women, which are not all equally effective and in some cases dangerous. The petitioner presents depictions and makes assertions regarding the effectiveness of several of these restraints, including a restraint which he patented.

III. NHTSA's Consideration of the Petition

A. General Principles

Motor vehicle safety standards must be practicable, meet the need for motor vehicle safety, and be stated in objective terms. 49 U.S.C. 30111(a). Petitions for rulemaking are governed by 49 CFR part 552. Pursuant to Part 552, the agency conducts a technical review of the petition, which may consist of an analysis of the material submitted, together with information already in possession of the agency. In deciding whether to grant or deny a petition, the agency considers this technical review as well as appropriate factors, which may include, among others, allocation of agency resources and agency priorities.

B. Analysis of the Petition

The agency's technical review of the petition had several main parts. First, the agency reviewed the petition and the sources it cited before conducting a comprehensive literature review, which included material from the early 1970s through the present. Additionally, the agency, as described above, conducted an updated review of crash data available from the NHTSA field databases, including NASS CDS. The agency considered all of the information contained in the petition, and for the reasons stated below, the agency is denying the petition.

The first part of Mr. Hofferberth's petition asks that NHTSA regulate the performance of supplementary automotive restraint systems for pregnant women. In assessing this aspect of the petition, NHTSA first attempted to quantify the safety problem, i.e., whether there is an

unreasonable risk of death or injury to pregnant women or to unborn children in a belted condition when exposed to a crash that would lead NHTSA to propose a performance requirement for supplemental restraint devices. The agency could not establish this through the technical review of the submitted petition materials.

For example, the petitioner asserts that unborn babies are in danger of being crushed by the lap belt portion of a seat belt during a frontal collision and that seat belts are not appropriate for use by pregnant women. However, the comprehensive UMTRI study showed that a pregnant woman's proper use of a seat belt has a positive effect on fetal outcome in a crash: "an 84 percent reduction in risk of adverse fetal outcome is obtained by properly wearing a seatbelt. On the basis of this relative risk and an overall belt use rate of 80 percent, unbelted pregnant occupants sustain an estimated 62 percent of all fetal losses in motor vehicle crashes." In addition, the amniotic fluid is capable of resisting the forces from the lap portion of a seat belt, and can aid in preventing the belt from penetrating through the unborn baby's body.

Similarly, the petitioner asserts that the lap belt portion of the restraint system causes fetal trauma in relatively minor crashes. However, as discussed above, a study[35] found that "[p]roper restraint use, with and without air bag deployment, generally leads to acceptable fetal outcomes in lower severity crashes," and went on to conclude that "compared to properly restrained pregnant occupants, improperly restrained occupants have a higher risk of adverse fetal outcome in lower severity crashes."

Additionally, the agency performed an updated review of crash data available from the NHTSA field databases, including NASS CDS. Although the petitioner asserts that unborn

[35] Klinich, K. D., Schneidier, L. W., Moore, J. L., Pearlman, M. D., entitled "Investigations of Crashes Involving Pregnant Occupants," dated 1999. This work was supported by General Motors Corporation, pursuant to an agreement with the U.S. Department of Transportation.

babies are in danger of being crushed by the lap belt portion of a seat belt and cites research that he argues shows a high rate of fetal and placental injury, the agency found that a low percentage (2.22 percent) of pregnant women lost their child after being exposed to a crash. The detailed review of all fetal demise cases indicated that all but one fell into the exclusion criteria used by UMTRI in their field data analysis. This one case was of an unbelted woman who sustained an AIS 5 complex uterus laceration caused by direct contact with the steering wheel.[36] Additional information regarding the analysis of NHTSA data for placental injury to belted pregnant women and the correlation of fetal mortality with higher crash severity, illustrating the beneficial effects of seat belt use by pregnant women, is provided above in section I.C.2. Accordingly, at this time the analysis of the field data does not indicate a safety need to propose a standard for supplemental restraints for pregnant women.

With regard to establishing performance requirements for supplemental restraints, NHTSA does not have sufficient information at this time to state whether there is any additional net safety benefit/disbenefit to be derived from their use or whether one type of device is superior to another. The agency notes that these devices are considered motor vehicle equipment, and manufacturers of these devices are subject to the recall and remedy requirements of the Motor Vehicle Safety Act (49 U.S.C. 30118-30120). To date NHTSA has not seen evidence of these devices causing harm to pregnant women. Artemis, the agency's central repository of data on motor vehicles and motor vehicle equipment defects, does not currently contain entries related to complaints or reported injuries resulting from the use of such devices.

Given the observed correlation between maternal and fetal outcome, the agency believes that improvements in crashworthiness, particularly advancements in occupant restraint systems,

[36] Case 2008-09-26 did involve a pregnant woman who experienced a placental abruption, but investigators were not able to determine whether the occupant had been wearing the belt correctly.

will serve to protect pregnant women and their unborn children. NHTSA continues to work towards these improvements through research efforts in the areas of advanced restraints and improvements to the Federal motor vehicle safety standards. The petitioner did not provide any data or testing to support the benefits of supplemental devices or the merits of the proposed test procedure to discriminate between good and bad performance to serve as a basis for such a performance requirement.

The second request in the petition asks that the agency warn pregnant women of the risk from the seat belt through a prominent warning label required in every vehicle. As noted in the Federal Register notice denying Mr. Hofferberth's 2005 petition to initiate rulemaking on a similar advisory placard (71 FR 14675), the agency disagrees with the claim that seat belts are hazardous to unborn babies. The agency position regarding the benefits of seat belts for both the mother and the unborn child has not changed since the publication of the 2006 denial notice and is supported, as discussed above, by the agency's review of the technical literature and field data.

As noted above, the agency conducted an extensive literature review and reviewed all sources cited by the petitioner. It is the agency's view that this literature shows that the most effective way to protect the unborn baby is to protect the pregnant woman. Technical studies were discussed in the preceding sections of this notice of decision. Additionally, the agency is not aware of any serious injuries to pregnant women caused by seat belts in non-impact situations, and the aforementioned 2008 Klinich paper showed that "[c]laims that restraints cause adverse fetal outcomes cannot be substantiated without reliable information on crash severity."

The agency's field data analysis shows, among other things, that seat belt-caused uterine or placental injuries during crashes are extremely rare (0.1 percent of cases) and that seat belt use dramatically reduces the risk of dying in a crash for both pregnant women and unborn children.

Additional information regarding the agency's field data analysis is provided above in section I.C.2.

Accordingly, for the reasons stated above, the petition is denied.

IV. Future Plans

A study showed that despite NHTSA recommending specific seat belt best practices for pregnant women, approximately one quarter of the pregnant women being studied did not follow the recommendation, and nearly two thirds of them had not received the information.[37] When asked about the effects of seat belts on their unborn babies during a motor vehicle collision, 34.0 percent of these same pregnant women were not sure, and another 10.7 percent believed that the seat belts would actually cause harm.[38] A study supported by the Federal Highway Administration reported that "[e]ducational level is a factor predicting seatbelt use. Among women with less than a high school education, 41 percent did not employ seatbelt restraints as compared with 18.8 percent who were high school graduates… [P]regnant women of lower educational level and socioeconomic status are at particular risk for failing to correctly employ seatbelts during pregnancy."[39]

Another recent study supported by the Eunice Kennedy Shriver National Institute of Child Health and Human Development, of the National Institutes of Health, reported that even though most pregnant women wear seat belts, those who do are not necessarily wearing them correctly. Additionally, this report states that despite ACOG's recommendation that all pregnant

[37] McGwin Jr., G., Willey, P., Ware, A., et al., entitled, "A Focused Educational Intervention Can Promote the Proper Application of Seat Belts during Pregnancy," published May 2004 in The Journal of Trauma Injury, Infection, and Critical Care.
[38] McGwin, Jr., G., Russell, S., Rux, R., et al., entitled, "Knowledge, Beliefs, and Practices Concerning Seat Belt Use During Pregnancy," published March 2004 in The Journal of Trauma Injury, Infection, and Critical Care.
[39] Taylor, A. J., McGwin Jr., G., Sharp, C. E., et al., entitled, "Seatbelt Use During Pregnancy: A Comparison of Women in Two Prenatal Care Settings," published June 2005 in the Maternal and Child Health Journal, Vol. 9, No. 2.

women receive prenatal seat belt counseling, not all women receive it. It also suggests that increased educational efforts emphasizing not only the use of seat belts but also their proper placement would be appropriate.[40]

The agency believes that it is very important to convey the importance of proper seat belt use to pregnant women. As indicated by the aforementioned studies, a large percentage of pregnant women are not following the current recommendations; therefore, NHTSA has decided to increase outreach efforts in this area. NHTSA currently posts the agency's official brochure, *If You are Pregnant: Seat Belt Recommendations for Drivers and Passengers,* on all official websites. It is a popular download from TrafficSafetyMarketing.gov,[41] the website for all NHTSA partners to find official publicity material. To increase the dissemination of this brochure, the agency plans to add it to the social networking outreach rotation of messages distributed through outlets such as Facebook and Twitter, and its content has been more prominently featured on Parents Central.[42] Proper seat belt use and seat positioning for pregnant women will also be the focus of an upcoming Safety in Numbers feature on the NHTSA website.

V. Conclusion

After carefully considering the safety need for the requested rulemaking and supporting information and in accordance with 49 CFR part 552, NHTSA hereby denies Mr. James E. Hofferberth's April 1, 2013 petition to regulate the performance of supplementary automotive restraint systems that are marketed specifically for pregnant women and to require prominent warning labels in all vehicles with the intent of informing pregnant women that "seat belts could

[40]Vladutiu, C. J., Weiss, H. B., entitled, "Motor Vehicle Safety During Pregnancy," published October 2011 in the American Journal of Lifestyle Medicine, Vol. 6, No. 3.
[41]http://www.trafficsafetymarketing.gov/CAMPAIGNS/Seat+Belts/Buckle+Up+America/Thanksgiving+Weekend/Pregnant+Women's+Guide+To+Buckling+Up
[42] http://www.safercar.gov/parents/SeatBelts/Pregnancy-Seat-Belt-Safety.htm

injure or kill their unborn child." Research and real-world data show the substantial benefits of seat belt use for both pregnant women and unborn children, and the agency recommends that all pregnant women wear properly adjusted seat belts.

The agency takes the safety of pregnant women very seriously and has already begun to increase awareness and educational efforts related to the proper use of seat belts while continuing to monitor the data trends surrounding this issue.

In accordance with 49 CFR part 552, this concludes the agency's review of the petition.

Authority: 49 U.S.C. 322, 30111, 30115, 30117, and 30162; delegation of authority at 49 CFR 1.95.

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under authority delegated in 49 CFR 1.95.

Raymond R. Posten,

Associate Administrator

for Rulemaking.

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